5

Risk Characterization

In this chapter, the risk characterization integrates the results of the exposure assessment (Chapter 3) with the results of the hazard characterization (Chapter 4) to estimate the risk of illness from *E. coli* O157:H7 in ground beef. The exposure assessment describes the probability of exposure to various doses of *E. coli* O157:H7 (e.g., number of *E. coli* O157:H7 organisms per ground beef serving). The hazard characterization derived a dose-response function to describe the probability of illness for these various doses. Characterization of the risk of illness from *E. coli* O157:H7 in ground beef is considered from several perspectives based on the following:

- Level of risk: individual, community, and population;
- Duration of exposure: per serving, per annum, and lifetime risk; and
- Population variability of risk: by season, age, or location.

This risk characterization also includes an analysis to identify factors (model inputs) that influence the occurrence and extent of *E. coli* O157:H7 contamination in combo bins, grinder loads, and ground beef servings and the subsequent risk of illness (model outputs). This type of analysis is generally referred to as a sensitivity analysis. Two types of sensitivity analyses are used in this risk assessment: (1) correlation analysis and (2) dependency analysis.

DEFINITION OF KEY TERMS

The following key terms are used throughout this chapter:

- Risk is the probability of the occurrence of an adverse outcome (e.g., illness or death) resulting from exposure to a hazard. In this risk assessment, risk refers to the probability of illness (number and severity) resulting from consuming a single ground beef serving contaminated with a specific number of *E. coli* O157:H7 organisms.
- Scope of the risk estimate refers to whether we are considering the risk of illness for an individual, a community, or an entire population.

- “Typical” individual risk refers to the probability of illness for an individual consuming a single serving of ground beef. In this risk characterization, the “typical” individual is defined as someone who purchases ground beef that is contaminated at the median concentration and stores and cooks that product in a way that is consistent with the median of the growth and cooking distributions (Table 5-1). This type of analysis does not apply to specific individuals.
- Community risk refers to the probability of illness for an entire community under a given exposure scenario. In this risk characterization, the risk is illustrated for a community exposed to a single grinder load contaminated with *E. coli* O157:H7.
- Population risk refers to the probability of illness from *E. coli* O157:H7 in ground beef across the U.S. population. This type of risk estimate is useful for guiding food safety policy decision making.
- Duration of exposure refers to the length of time (e.g., per serving, per annum, or lifetime) for which a risk estimate was assessed.
- Risk per serving refers to the risk of *E. coli* O157:H7 illness from consuming a single serving of ground beef.
- Risk per annum refers to the risk of *E. coli* O157:H7 illness from consuming ground beef over the course of a year.
- Lifetime risk refers to the risk of *E. coli* O157:H7 illness from consuming ground beef over the course of a lifetime.
- Dose is the number of *E. coli* O157:H7 organisms in a single serving of ground beef.
- Population risk by season, age, and location refers to the stratified characterization of the risk of illness from *E. coli* O157:H7 in ground beef to provide further insight regarding the public health risks to specific subpopulations (e.g., based on seasonal exposure, age, and consumption patterns).
- Factors are model inputs that influence the prevalence and number of *E. coli* O157:H7 in ground beef or, more generally, influence the overall risk of *E. coli* O157:H7-related illness from ground beef. These model inputs may include one or more of the following: production practices, time and temperature controls during processing, storage and handling practices for ground beef during retail and preparation, or how thoroughly a ground beef serving was cooked.
- Sensitivity analysis refers to the quantitative process of identifying factors (model inputs) in the farm-to-table continuum that contribute to the occurrence of *E. coli* O157:H7 in ground beef or the subsequent risk of illness.
- Correlation analysis is one type of sensitivity analysis used to identify uncertain factors (model inputs) that influence either the occurrence of *E. coli* O157:H7 in ground beef or the subsequent risk of illness (model outputs). This type of sensitivity analysis identifies important factors quickly but only works for those that are uncertain.
- Dependency analysis is another type of sensitivity analysis used to identify factors (model inputs) that influence either the occurrence of *E. coli* O157:H7 in ground beef or the subsequent risk of illness (model outputs). This type of sensitivity analysis is resource intensive but identifies both uncertain and certain factors (model inputs) in the risk assessment model.

RISK OF ILLNESS FROM *E. COLI* O157:H7

The estimated risk of illness from *E. coli* O157:H7 in ground beef varies depending on the level at which the risk estimate is focused—that is, whether one considers the risk of illness for an individual consuming a single serving of ground beef; a community of individuals experiencing similar exposures to *E. coli* O157:H7 in ground beef that came, for example, from the same grinder load; or the risk of illness across the entire U.S. population. The estimated risk of *E. coli* O157:H7 illness also varies depending on the duration of exposure—that is, whether one considers the risk of illness on a per serving, per annum, or lifetime basis. To characterize the risk of illness from *E. coli* O157:H7 in ground beef, it is important to clearly define the type of risk estimate under consideration (e.g., individual lifetime risk of illness versus a population per annum risk of illness). The type of risk estimate developed depends on the problem under consideration for which the risk assessment was developed: to estimate the median health risk to individuals, better understand an outbreak scenario, or develop food safety policy. Several types of risk estimates are considered below.

Risk of Illness for an Individual

A "typical" individual's risk of *E. coli* O157:H7 illness from ground beef can be calculated from point estimates taken from output distributions in the exposure assessment combined with the median (50th percentile) *E. coli* O157:H7 dose-response curve (Table 5-1). Using this approach, a "typical" individual's probability of being exposed to a single *E. coli* O157:H7 organism in ground beef is somewhere between 1 in 1,500 (6.9×10^{-4}) and 1 in 1 million (9.2×10^{-7}).[1] Using the median dose-response curve for *E. coli* O157:H7, this equates to a lifetime risk of *E. coli* O157:H7 illness from ground beef for the "typical" individual that is between 1 in 8 million [$(6.9 \times 10^{-4})(1.7 \times 10^{-4}) = 1.17 \times 10^{-7}$] and 1 in 6 billion [$(9.2 \times 10^{-7})(1.7 \times 10^{-4}) = 1.56 \times 10^{-10}$].[2] Using similar calculations, the annual "typical" individual's risk of *E. coli* O157:H7 illness from ground beef is somewhere between 1 in 600 million and 1 in 400 billion.

This illustration is for the "typical" individual; it assumes that an individual always purchases the median product and always stores and cooks ground beef in accordance with the median of the population. If such an individual were typical of all individuals in the United States, the risk of *E. coli* O157:H7 would be extremely small for the entire population. Such an individual does not, of course, actually exist. The risk of illness for a specific individual from a specific serving of ground beef depends on when and where the ground beef was produced, how it was stored and handled, and how it was cooked. It also depends on the consumption patterns of the specific individual—how much (serving size) and how often (frequency) a specific individual consumes ground beef. Moreover, a specific individual may be more or less susceptible to illness or severe consequences of illness if exposed to *E. coli* O157:H7 in ground beef than predicted using the median dose-response curve. Consequently, a specific individual's risk of *E. coli* O157:H7

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[1] A "typical" individual's probability of consuming ground beef with at least 1 *E. coli* O157:H7 organism is calculated as follows: $10^{\text{(log[number of contaminated ground beef servings purchased over a lifetime) + log(number of organisms per contaminated serving) + (change in the number of } E.\ coli \text{ O157:H7 organisms in a serving of ground beef from storage conditions) + (decrease in the number of } E.\ coli \text{ O157:H7 organisms in ground beef from cooking)]}}$. The data used in this calculation are presented in Table 5-1.

[2] This is calculated based on multiplying the probability of exposure to a particular number of *E. coli* O157:H7 organisms in a ground beef serving (dose) by the probability of illness (response) given this exposure (dose) (Table 5-1).

TABLE 5-1. Data from the Exposure Assessment (Chapter 3) and Hazard Characterization (Chapter 4) Are Used to Estimate the Risk of *E. coli* O157:H7 Illness for a "Typical" Individual

Information Used to Estimate the Risk of *E. coli* O157:H7 Illness for a "Typical" Individual	
1. General Information	
• U.S. population:	260 million
• Annual number of ground beef servings:	18.2 billion (Tables 3-24, 3-25, and 3-26)
2. Typical Individual	
• Average lifetime:	70 years
• Average serving size of ground beef:	87 grams (Tables 3-24, 3-25, and 3-26)
• Average number of ground beef servings purchased annually:	70 servings (18.2 billion servings/260 million people; Tables 3-24, 3-25, and 3-26)
3. *E. coli* O157:H7 Contamination in Uncooked Ground Beef Servings	
• Probability of a contaminated ground beef serving:	0.2% to 0.5% (5th and 95th percentiles) (Figure 3-27 and Equation 3-40)
• Typical level of contamination per serving:	1 to 3 *E. coli* O157:H7 organisms (5th and 95th percentiles) (Figure 3-27 and Equation 3-40)
• Typical number of contaminated servings purchased in a lifetime:	9 to 23 servings
4. Typical Growth and Decline in the Number of *E. coli* O157:H7 during Storage, Handling, and Cooking	
• Increase in the number of *E. coli* O157:H7 during storage and handling conditions:	0 logs (Figure 3-23)
• Decrease in the number of *E. coli* O157:H7 from freezing:	1 log (Table 3-18)
• Decrease in the number of *E. coli* O157:H7 from cooking:	5 to 6 logs (Figure 3-20)
5. Dose-Response Curve (median)	Figure 4-6

illness may be very different from a "typical" individual's risk of *E. coli* O157:H7 illness. Characterization of risk of *E. coli* O157:H7 illness for the "typical" individual, however, is useful in understanding that the overall risk is low. However, specific individuals may be at greater or lower risk of *E. coli* O157:H7 illness because of differences in consumer and retail behavior practices (storage, handling, and preparation conditions for ground beef); susceptibility to illness; or changes in production, slaughter, or retail practices that lead to either more contaminated ground beef servings (increased prevalence) or a greater number of *E. coli* O157:H7 organisms in contaminated ground beef servings. Some of these influence variables will be considered in the "Population Risk by Season, Age, and Location" section.

Risk of Illness for a Community—Simulated Outbreak

Characterizing the risk of *E. coli* O157:H7 illness from ground beef for a community is useful in evaluating the likelihood of a foodborne outbreak and the factors that would contribute to such an outbreak. As an example, consider a community exposed to a large amount of *E. coli* O157:H7-contaminated ground beef from a single grinder load that is stored and cooked under the same conditions (e.g., it was purchased, handled, and prepared by a single retail establishment).

This *E. coli* O157:H7 risk assessment indicates that grinder loads of ground beef can have concentrations of *E. coli* O157:H7 as high as 1 organism per 100 grams.[3] Given an average serving size of 87 grams,[4] nearly all servings of ground beef generated from such a grinder load would contain at least 1 *E. coli* O157:H7 organism. This risk assessment predicts growth of *E. coli* O157:H7 in ground beef in only 1% to 2% of storage scenarios (Figure 3-23), and only about 1 in 1,000 ground beef servings will have *E. coli* O157:H7 organisms grow to a level of 5.5 logs. Nevertheless, if all of the ground beef servings generated from the grinder load in this example were stored (e.g., refrigerated) in a manner that allowed growth of *E. coli* O157:H7, then each ground beef serving could contain a substantial number of *E. coli* O157:H7 organisms prior to cooking.[5] If all of these ground beef servings were undercooked, reducing the number of *E. coli* O157:H7 organisms in each ground beef serving by only 3 logs,[6] then each ground beef serving for consumption would be expected to contain about 270 *E. coli* O157:H7 organisms.[7] If individuals consume only one serving of *E. coli* O157:H7-contaminated ground beef, then about 3,200 people would be expected to become ill from *E. coli* O157:H7.[8] On the other hand, if all of these ground beef servings had been subjected to similar cooking conditions that resulted in a decrease of 5.5 logs,[9] only 12 people would be expected to become ill from *E. coli* O157:H7.

This example illustrates how an outbreak might develop in a community. It is not difficult to imagine that a single grinder load might be distributed to a single community. In fact, local commercial preparers of ground beef might receive, store, and cook volumes of ground beef consisting of entire grinder loads. A similar scenario occurred in the northwestern U.S. outbreak described in Chapter 4 (Tuttle et al. 1999; Bell et al. 1994). While such outbreaks are uncommon, sporadic illness often results from individual ground beef servings following "high risk" scenarios (e.g., improper storage, handling during processing, distribution, retail and preparation, or undercooking of ground beef servings). Characterizing the per serving risk of *E.*

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[3]The *E. coli* O157:H7 risk assessment predicts that ground beef servings from grinder loads containing more than 1 *E. coli* O157:H7 organism have a 0.0116% probability of occurring.

[4]Calculated as the weighted average of the amount of ground beef (in grams) consumed by an individual for each age category. See Tables 3-24, 3-25, and 3-26.

[5]About 5.5 logs of *E. coli* O157:H7 in each ground beef serving.

[6]The *E. coli* O157:H7 risk assessment predicts that 3 logs or less occurs 25% of the time.

[7]This is calculated from Equation 3-42: $DOSE_{pop} = BACT_{pop} + Growth_{pop} - LR_{pop}$, where the number of *E. coli* O157:H7 organisms per ground beef serving (dose) is equal to the number of *E. coli* O157:H7 in an uncooked ground beef serving (multiplied by the number of servings) plus the increase in the number of *E. coli* O157:H7 organisms during storage and handling minus the decrease in *E. coli* O157:H7 organisms as a result of cooking. In this scenario, $DOSE_{pop} = BACT_{pop} + Growth_{pop} - LR_{pop} = \log_{10}(0.01 \times 87) + 5.5 - 3 = 2.44$ logs in each cooked ground beef serving (= 275 *E. coli* O157:H7 organisms in each cooked ground beef serving).

[8]Calculated by using the dose-response equation (Equation 4-3) for ground beef servings containing 270 *E. coli* O157:H7 organisms and multiplying by the total number of ground beef servings from this grinder load (78,000 servings).

[9]The *E. coli* O157:H7 risk assessment predicts that this level of cooking (e.g., resulting in a 5.5 log reduction in *E. coli* O157:H7 organisms in each ground beef serving) is the median of the cooking distribution.

coli O157:H7 illness from ground beef within a community is useful for evaluating the conditions that are likely to lead to a foodborne outbreak.

Risk of Illness for the U.S. Population

The annual risk of *E. coli* O157:H7 illness from ground beef within the U.S. population can be estimated by considering the entire exposure assessment distribution (e.g., the probability of consuming *E. coli* O157:H7 in ground beef for all possible doses). When the median exposure distribution and the median dose-response function are used, the risk of illness at each exposure dose can be calculated as the product of these two distributions (Table 5-2).

TABLE 5-2 Risk of Illness for U.S. Population Using Median Exposure and Dose-Response Distributions

Log of *E. coli* O157:H7 per Serving	Number of *E. coli* O157:H7 per Serving	Probability of Exposure (Ex)	Probability of Illness Given Exposure (DR)	Risk of Illness (Ex × DR)
0.0	1	5.5×10^{-05}	1.7×10^{-04}	9.5×10^{-09}
0.5	3	2.9×10^{-05}	5.5×10^{-04}	1.6×10^{-08}
1.0	10	6.1×10^{-06}	1.7×10^{-03}	1.0×10^{-08}
1.5	32	1.2×10^{-06}	5.4×10^{-03}	6.5×10^{-09}
2.0	100	7.7×10^{-07}	1.6×10^{-02}	1.3×10^{-08}
2.5	316	5.3×10^{-07}	4.7×10^{-02}	2.5×10^{-08}
3.0	1,000	4.3×10^{-07}	1.2×10^{-01}	5.0×10^{-08}
3.5	3,162	3.4×10^{-07}	2.3×10^{-01}	7.7×10^{-08}
4.0	10,000	2.7×10^{-07}	3.6×10^{-01}	9.7×10^{-08}
4.5	31,623	2.2×10^{-07}	4.8×10^{-01}	1.1×10^{-07}
5.0	100,000	1.8×10^{-07}	5.8×10^{-01}	1.0×10^{-07}
5.5	316,228	1.5×10^{-07}	6.6×10^{-01}	1.0×10^{-07}
6.0	1,000,000	1.2×10^{-07}	7.3×10^{-01}	8.9×10^{-08}
6.5	3,162,278	9.7×10^{-08}	7.8×10^{-01}	7.6×10^{-08}
7.0	10,000,000	7.4×10^{-08}	8.2×10^{-01}	6.1×10^{-08}
7.5	31,622,777	5.4×10^{-08}	8.6×10^{-01}	4.6×10^{-08}
8.0	100,000,000	3.8×10^{-08}	8.9×10^{-01}	3.4×10^{-08}
8.5	316,227,766	2.5×10^{-08}	9.1×10^{-01}	2.3×10^{-08}
9.0	1,000,000,000	1.4×10^{-08}	9.3×10^{-01}	1.3×10^{-08}
9.5	3,162,277,660	4.8×10^{-09}	9.4×10^{-01}	4.5×10^{-09}
10.0	10,000,000,000	8.5×10^{-10}	9.5×10^{-01}	8.1×10^{-10}
10.5	31,622,776,602	5.5×10^{-11}	9.6×10^{-01}	5.3×10^{-11}
11.0	100,000,000,000	2.0×10^{-12}	9.7×10^{-01}	1.9×10^{-12}
Population risk of illness from *E. coli* O157:H7 per serving				9.6×10^{-07}

Table 5-2 shows this population risk to be nearly 1 illness in each 1 million (9.6×10^{-7}) servings of ground beef consumed annually. At each half-log dose interval, the risk of becoming ill depends on the probability of being exposed to that dose and the probability of illness given that dose. When the entire exposure distribution is considered, the sum of the risk of illness across all doses represents the population risk. This annual U.S. population risk estimate is based on the central tendencies (median) of both the exposure distribution and dose-response functions.[10]

This risk of illness, 9.6×10^{-7} illnesses per serving, is comparable to the findings of Cassin et al. (1998) and Marks et al. (1998). Cassin et al. (1998) conducted a quantitative risk assessment of *E. coli* O157:H7 in ground beef hamburgers cooked at home, for Canada, and calculated a mean per serving risk of illness of 5.1×10^{-5} for adults and 3.7×10^{-5} for children. The probability of illness generated by another risk assessment of *E. coli* O157:H7 in ground beef in the United States ranged from 3×10^{-4} to 7×10^{-8} (Marks et al. 1998). The risk of illness predicted from this risk assessment ranges from 3.3×10^{-7} to 2×10^{-6} per serving (median, 9.6×10^{-7}) (Table 5-2).

Given approximately 18.2 billion servings of ground beef consumed per year, the risk assessment predicts about 17,500 cases of *E. coli* O157:H7 illness per year (50th percentile). The median number of cases per year predicted from public health surveillance data in the hazard characterization is approximately 19,000. Because the uncertainty distributions describing the exposure distribution (e.g., the probability of an *E. coli* O157:H7 dose in a ground beef serving) and dose-response function (e.g., the probability of illness given a dose of *E. coli* O157:H7 in a ground beef serving) are not symmetrical, these two estimates of illness do not precisely correspond (i.e., the median of the product of these two random variables does not equal the product of their respective median values because these distributions are asymmetric).

Risk of Severe E. coli O157:H7 Illness

Given this population risk of *E. coli* O157:H7 illness from ground beef, the probability of severe illnesses can be estimated. As noted in Chapter 4, about 20% of all cases develop bloody diarrhea and 49% of these cases seek medical attention. Of those persons who develop bloody diarrhea and seek medical attention, about 21.6% are severe enough to be hospitalized. Of these hospitalized cases, about 24% are hemolytic uremic syndrome (HUS) cases and about 12% of those cases result in death. The population risk of being hospitalized but recovering is 2.0×10^{-8}, the population risk of developing HUS but recovering is 4.2×10^{-9}, and the population risk of death is 5.9×10^{-10} per ground beef serving. These outcomes of *E. coli* O157:H7 illness, which represent the severest forms of this disease for humans, occur very infrequently on a “per serving” basis. If 18.2 billion servings of ground beef are consumed per year, these population risks imply that, on an “per annum” basis, 370 people are hospitalized but recover, 87 people develop HUS but recover, and 11 people die as a result of *E. coli* O157:H7-contaminated ground beef.

Risk of E. coli O157:H7 Illness as a Function of Exposure (Dose)

The risk of human illness from *E. coli* O157:H7 in ground beef is the result of two divergent trends:

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[10]Uncertainty about this risk ranges from about 1 illness in every 3 million consumed ground beef servings at the 5th percentile to about 2 illnesses in every 1 million consumed ground beef servings at the 95th percentile.

1. Consumers are more likely to be exposed to a lower rather than a higher number of *E. coli* O157:H7 organisms (dose) in a ground beef serving (Figure 3-29; Table 5-2); and
2. Consumers are more likely to become ill when exposed to a higher rather than a lower number of *E. coli* O157:H7 organisms (dose) (Figure 4-7; Table 5-2).

These divergent trends are observed in Table 5-2, which shows that increasing dose (e.g., number of *E. coli* O157:H7 organisms) is associated with decreasing probability of exposure and increasing probability of illness. Therefore, the change in risk of illness as dose increases is dependent on the rate at which exposure probability is declining and the dose-response probability is increasing. Figure 5-1 uses the information in Table 5-2 to show how the risk of illness from *E. coli* O157:H7 changes as dose changes.

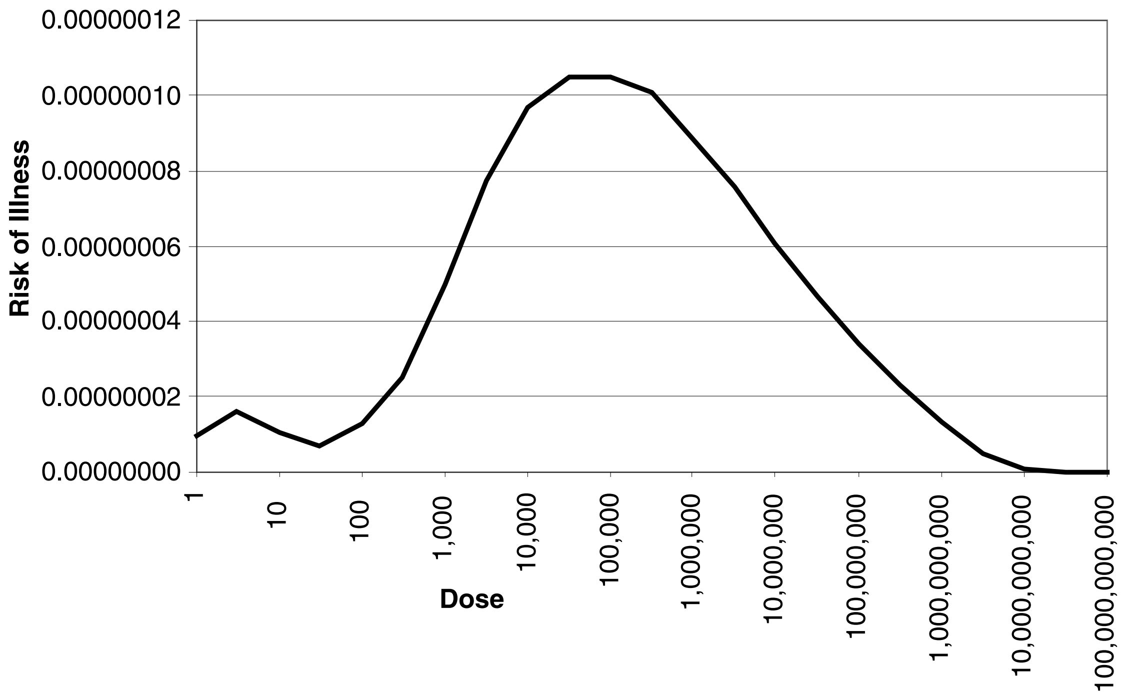


FIGURE 5-1 Risk of illness for U.S. population by dose.

Figure 5-1 shows that the highest risk of illness is associated with doses around 100,000 *E. coli* O157:H7 organisms per serving. Although the probability of exposure is greatest at a dose of 1 organism per ground beef serving (5.5×10^{-05}), the dose-response function predicts a very low probability of human illness given an exposure of just 1 *E. coli* O157:H7 organism (1.7×10^{-04}). This results in a low risk of illness ($5.5 \times 10^{-05} \times 1.7 \times 10^{-04} = 9.5 \times 10^{-09}$). At a dose of 100,000 organisms per ground beef serving, however, the probability of exposure is much lower (1.8×10^{-07}), but the probability of illness is much higher (0.58). Consequently, the risk of illness from exposure to 100,000 *E. coli* O157:H7 organisms ($1.8 \times 10^{-07} \times 0.58 = 1.0 \times 10^{-07}$) is higher than from exposure to 1 *E. coli* O157:H7 organism.

One interpretation of Figure 5-1 is that reducing the number of *E. coli* O157:H7-contaminated ground beef servings, but not the number of *E. coli* O157:H7 organisms in a ground beef serving, would lower the risk of illness at each dose level (i.e., decrease the amplitude of the curve). Such a reduction might occur by improved controls in the slaughter process that result in fewer contaminated ground beef servings. Alternatively, improved storage and/or cooking behavior by consumers and food preparers would decrease the number of *E. coli*

O157:H7 organisms in contaminated ground beef servings but not change the total number of contaminated servings (i.e., shift the curve to the left but leave the amplitude unchanged). Either reducing the number of *E. coli* O157:H7-contaminated ground beef servings or the number of *E. coli* O157:H7 organisms in contaminated ground beef servings would result in a reduction in the number of *E. coli* O157:H7 illnesses occurring per year.

Figure 5-1 indicates that reducing the number of *E. coli* O157:H7-contaminated servings actually results in a greater reduction in risk relative to reducing the number of *E. coli* O157:H7 in contaminated ground beef servings. A tenfold reduction in the number of *E. coli* O157:H7-contaminated ground beef servings results in a population risk of 9.6×10^{-08} per serving. A tenfold reduction in the number of *E. coli* O157:H7 organisms in contaminated ground beef servings results in a population risk of 5.5×10^{-07} per serving. This suggests that interventions focused on reducing the prevalence of *E. coli* O157:H7 (e.g., improved controls during slaughter and processing) are more effective at reducing the risk of illness than those focused on reducing the number of *E. coli* O157:H7 in consumed ground beef servings (i.e., storage and cooking conditions). However, this analysis does not suggest which intervention, if either, is more feasible to achieve.

The preceding discussion illustrates that a population estimate of risk is the sum of the risks faced by all individuals in the population. Therefore, the population risk estimate should be interpreted as a summary measure of risk that can be used for policy analysis or comparison with other risk estimates. The population risk is not indicative of the risk for any one individual. In other words, it is incorrect to assume that, given a population risk of 1 illness in every 1 million servings, each serving a person consumes has this risk of illness. Individual consumer risk is not necessarily random. The risk of illness from a serving of ground beef for a specific consumer can depend on when and where the ground beef was produced, how it was stored, and how the serving was cooked. The specific consumer may also be more susceptible to illness or severe consequences of illness if exposed. These factors are not necessarily controllable by the individual, but they are also not necessarily randomly occurring. The next sections consider the influence of such factors on the risk of illness from *E. coli* O157:H7 in ground beef.

POPULATION RISK BY SEASON, AGE, AND LOCATION

The risk of illness from *E. coli* O157:H7 in ground beef can vary among U.S. subpopulations based on differences in exposure (by seasonal contamination or behavioral differences) or host susceptibility (by age). Characterization of the risk of illness from *E. coli* O157:H7-contaminated ground beef can be used to target intervention strategies and risk communication messages. This risk assessment considers the risk of illness by seasonal exposure, age of the consumer, and location of the meal.

Variability in the Risk of Illness by Season

Variability in seasonal exposure may influence the risk of illness from *E. coli* O157:H7 in ground beef. The exposure assessment predicts that consumers are exposed to more *E. coli* O157:H7-contaminated ground beef servings during the "high prevalence season" (June to September) than during the "low prevalence season" (October to May) (see Chapter 3). This seasonal trend in exposure to *E. coli* O157:H7 in ground beef may be associated with the increased number and severity of *E. coli* O157:H7 cases reported during June through September (see Chapter 2).

The risk of illness is substantially greater in the high prevalence season at all doses relative to the low prevalence season. Figure 5-2 compares the risk of illness between the low and high prevalence seasons using the median exposure distribution for each season and the median dose-response function. For a dose of *E. coli* O157:H7 in ground beef servings ranging from 1 to 10 logs, each curve shows the product of the probability of exposure to that dose and the probability of illness given that dose. Both high and low prevalence seasons have similar shaped distribution curves for illness and are consistent with the shape shown in Figure 5-1. This indicates that the risk of illness from *E. coli* O157:H7 in ground beef servings follows the same trend over the same dose range.

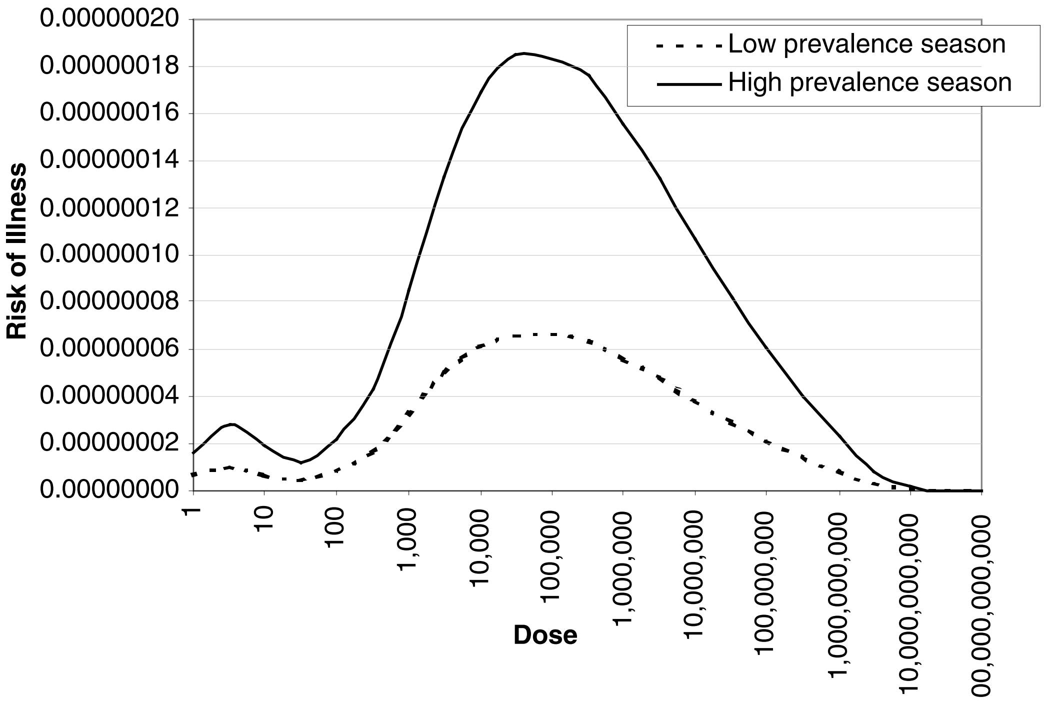


FIGURE 5-2 Risk of illness for U.S. population by dose for low and high prevalence seasons.

The only influence of season in this risk assessment occurs because live cattle, carcasses, and ground beef are more contaminated in the high prevalence season (June to September). No data were available on possible seasonal differences in consumer or retail storage and preparation of ground beef meals (e.g., grilled hamburgers in July versus baked meat loaf in November). Similarly, no data were available on seasonal consumption patterns for ground beef. Seasonal consumption data would provide information on how much ground beef was consumed and in what form (e.g., ground beef patty, meat loaf, or meatballs) during June to September versus other months of the year.[11] As a result, the similar shape of the two curves in Figure 5-2 simply reflects the assumption of similar consumer behavior practices (storage and cooking) for both high and low prevalence seasons.

[11] The type of ground beef meal consumed is important because ground beef meals are handled and cooked differently (e.g., ground beef patties consumed on the Fourth of July may have more time-temperature abuse at a picnic and are more likely to be undercooked on a grill than meat loaf consumed in January that may have been baked in the oven).

The greater prevalence of contaminated ground beef servings in the high prevalence season is reflected in the greater risk of illness across all doses. When the risk of illness is summed across all doses, the population risk of illness is 1.7×10^{-6} in the high prevalence season and 6.0×10^{-7} in the low prevalence season. Therefore, about 1 in every 600,000 servings consumed during the high prevalence season is predicted to result in illness, while about 1 in every 1.6 million servings consumed in the low prevalence season results in illness. These differences imply that risk of illness is about three times greater in the high prevalence season than in the low prevalence season.

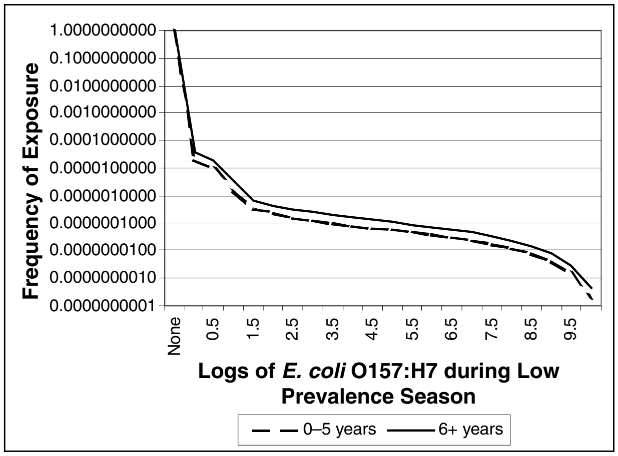
The hypothetical linkage between live cattle, ground beef, and human *E. coli* O157:H7 illnesses is strongly supported by these seasonal findings. Of the 18.2 billion ground beef servings consumed annually, it is assumed that one-third are consumed during the high prevalence season and two-thirds are consumed during the remainder of the year. Combining this consumption pattern information with the seasonal risk per ground beef serving estimates implies that 58% of illnesses occur during the high prevalence season, while 42% occur during the low prevalence season. This finding is consistent with FoodNet data that show 64% of illnesses occur during June through September. Such consistency is noteworthy because the model only accounts for seasonality in live cattle and grinder loads of ground beef. Therefore, without any adjustment for seasonal differences in ground beef storage or cooking, these results imply that seasonal changes in prevalence on the farm subsequently influence levels of *E. coli* O157:H7 in combo bins, grinders loads, and servings and predict changes in illnesses in a manner consistent with human health surveillance data. Furthermore, these results suggest that variability in consumer behaviors may contribute to an increased number of *E. coli* O157:H7 illnesses observed in the summer months. Further research on consumer and retail behaviors is needed to validate the assumption that improper storage and cooking practices (e.g., time and temperature abuses) for ground beef are more likely during the summer months.

Variability in the Risk of Illness by Age of the Consumer

Age of the consumer has been identified as a risk factor for illness from *E. coli* O157:H7 in ground beef. In hazard characterization (Chapter 4), a higher apparent incidence of *E. coli* O157:H7 illnesses was reported for 1- to 9-year-olds. Other data suggest that most of the elevated risk occurs in children 0 to 5 years old (Mead et al. 1999).

The exposure assessment was used to generate an exposure distribution for children 0 to 5 years old and persons 6 years and older (Figure 5-3). The exposure distribution for 0- to 5-year-olds is shifted slightly to the left, reflecting a smaller average ground beef serving size (44 grams) compared with the average serving size for all other ages (90 grams). Because of the smaller serving size, children under 5 years old are less likely to be exposed to *E. coli* O157:H7 organisms in ground beef (i.e., they have a lower probability of consuming an *E. coli* O157:H7-contaminated ground beef serving and, if a contaminated serving is consumed, it is likely to have a lower number of *E. coli* O157:H7 organisms).

Although children 0 to 5 years old are less likely than older persons to be exposed to *E. coli* O157:H7 in ground beef, they are disproportionately represented among all reported *E. coli* O157:H7 cases. If young children are less exposed to *E. coli* O157:H7 in ground beef but more likely to become ill from *E. coli* O157:H7, then they may be (1) more susceptible to illness from the exposures they experience, (2) more likely to be diagnosed by a physician than other age



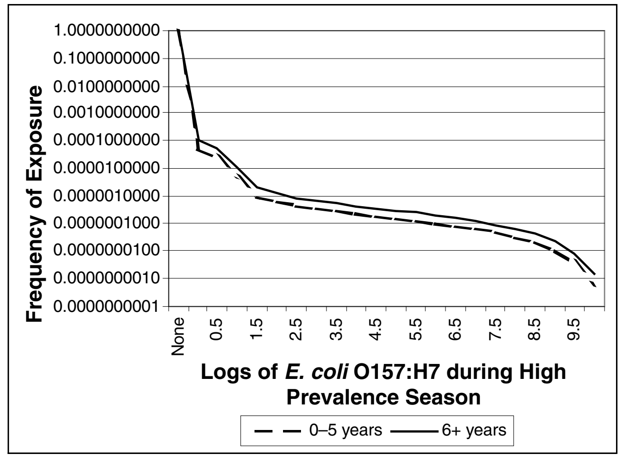


FIGURE 5-3 Comparison of predicted seasonal exposure distributions for children 0 to 5 years old versus people 6 years and older.

groups, or (3) more exposed to other sources of *E. coli* O157:H7 (e.g., daycare, petting farm, swimming pool) than the remainder of the population.[12]

If children ages 0 to 5 are more susceptible to illness from *E. coli* O157:H7, then a more sensitive dose-response curve than that derived for the general population should be used. Nevertheless, no data are available to estimate a different dose-response function for young children. If the upper bound *E. coli* O157:H7 dose-response curve derived from *Shigella dysenteriae* surrogates is used, then the risk of illness for children 0- to –5-years-old is estimated to be 2.4×10^{-6} per ground beef serving. This is comparable to estimates by Cassin et al. (1998) for the average (mean) risk of illness for children of 3.7×10^{-5} per ground beef serving. If young children are more susceptible to illness from *E. coli* O157:H7-contaminated ground beef, then their risk may be up to 2.5 times greater than that of the general U.S. population (2.4×10^{-6} versus 9.6×10^{-7}). Children 0- to 5-years-old consume only about 7% of all ground beef servings, but a more susceptible dose-response curve implies that about 15% of all illnesses occur in this age category.

Young children may be more susceptible to illness when exposed to *E. coli* O157:H7, but the available data do not rule out the possibility that reported illnesses for children are affected by various surveillance biases. For example, it is possible that the etiologic fraction of *E. coli* O157:H7 cases attributed to ground beef for young children may be lower than that reported for the general population. For instance, young children are exposed to *E. coli* O157:H7 via child-care facilities. This route of exposure may be important for this age group and would reduce the etiologic fraction of cases attributed to ground beef. Furthermore, adjustments to reported cases used for the general population may overestimate the proportion of cases in young children. It seems likely that young children are more likely than older persons to see a health care worker when they are sick. For example, young children are also more likely to develop HUS, and such a severe illness certainly requires medical attention. Based on the available data, however, the existence and magnitude of these biases cannot be ascertained.

[12]Exposure to other sources of *E. coli* O157:H7 may confound the etiologic fraction of *E. coli* O157:H7 cases attributable to ground beef (Chapter 4).

Variability in the Risk of Illness by Location of Meal

As more meals are consumed outside the home in the United States, there is a growing interest in the relative risk of foodborne illness from eating at home versus “away from home” (HRI). The 1994–1996, 1998 Continuing Survey of Food Intakes by Individuals indicates that 65% of ground beef meals are consumed outside the home (e.g., Tables 3-24, 3-25, and 3-26). While this risk assessment includes data on where ground beef meals were consumed, data on variability in food preparation behavior between consumers (home) and food preparers (HRI) are lacking. These data are needed to estimate the amount of *E. coli* O157:H7 contamination (dose) in ground beef servings prepared at home and at HRI. While it is plausible that HRI preparation practices for ground beef are more stringent under the Food Code (FDA 1999), data are needed to support such an assumption. Storage and cooking time and temperature data are available for ground beef meals cooked at home (Audits International 1999). When HRI storage and cooking time and temperature data become available, the risk of illness from home-prepared and HRI-prepared ground beef servings can be compared. The effects of consumer storage and cooking practices on the risk of *E. coli* O157:H7 illness from ground beef will be further evaluated in the context of sensitivity analysis.

Other Population Risk Variability

As more data become available, a more detailed picture of the risk of illness from *E. coli* O157:H7 in ground beef within the U.S. population can be developed. The level of detail needed in a risk characterization depends on the type of problem under consideration.

SENSITIVITY ANALYSIS

Sensitivity analysis refers to the quantitative process of identifying factors (model inputs) that are most responsible for influencing the occurrence and extent of *E. coli* O157:H7 in ground beef (model outputs). A combination of statistical, algebraic, and graphical techniques is used to illustrate the effect of sensitive factors on model outputs. Two types of sensitivity analyses are used in this risk assessment: correlation analysis and dependency analysis.

Correlation Analysis

Correlation analysis is used to identify “uncertain” factors (i.e., model inputs for which there are limited data and information) that influence intermediate and final model outputs. Factors that are supported by data and information (i.e., not “uncertain”) are identified by dependency analysis (discussed in the next section). Therefore, correlation analysis is but one technique for identifying factors most important in influencing the likelihood of exposure or risk of illness.

Correlation analysis was used to identify “uncertain” factors most important in influencing the occurrence and extent of *E. coli* O157:H7 contamination in ground beef at various points along the farm-to-table continuum:

- *E. coli* O157:H7 in combo bins created from steer/heifer carcasses,
- *E. coli* O157:H7 in combo bins created from cow/bull carcasses,
- *E. coli* O157:H7 in grinder loads,
- *E. coli* O157:H7 in ground beef servings prior to storage and cooking, and
- *E. coli* O157:H7 in ground beef servings after storage and cooking.

For each of these outputs, correlation was measured relative to the number of *E. coli* O157:H7 organisms within a unit (i.e., combo bin, grinder load, or single serving) and the prevalence (%) of *E. coli* O157:H7-contaminated units (i.e., combo bins, grinder loads, servings). The mean number of *E. coli* O157:H7 organisms in a unit (e.g., combo bin) was estimated for each output. Factors were identified as correlated to the output if the Spearman rank correlation coefficient was greater than 0.30.

E. coli O157:H7 in Combo Bins Created from Steer/Heifer Carcasses

The size of the *E. coli* O157:H7-contaminated carcass surface area was the only factor correlated (coefficient = 0.33) with the number of *E. coli* O157:H7 organisms in steer/heifer combo bins (Table 5-3). This correlation only applied to the high prevalence season (June to September). There was no correlation between the extent of carcass contamination and the resulting number of *E. coli* O157:H7-contaminated steer/heifer combo bins. Uncertainty regarding the size of *E. coli* O157:H7 contamination area on carcasses ranged from 40 cm^2 (5th percentile) to 900 cm^2 (95th percentile).

TABLE 5-3 Correlations with *E. coli* O157:H7 Contamination in Steer/Heifer Combo Bins

E. coli O157:H7 Contamination in Steer/Heifer Combo Bins	Output Correlations with the Number of *E. coli* O157:H7 Organisms in a Unit and the Percent of Units Contaminated (%) by Season			
	June to September (High Prevalence Season)		October to May (Low Prevalence Season)	
Model Input (factor)	No.	%	No.	%
Area of carcass contaminated	0.33			

E. coli O157:H7 in Combo Bins Created from Cow/Bull Carcasses

Factors that most influence the occurrence and extent of *E. coli* O157:H7 contamination in cow/bull combo bins are the size of the *E. coli* O157:H7-contaminated carcass surface area and the average (mean) effect of chilling on contaminated carcasses (Table 5-4). The change in the number of *E. coli* O157:H7 organisms resulting from chilling was modeled as a normal distribution with an uncertain mean ranging from –0.5 to +0.5. The effect of chilling the carcasses was correlated with the number of *E. coli* O157:H7-contaminated cow/bull combo bins but not with the number of *E. coli* O157:H7 in these combo bins.

E. coli O157:H7 in Grinder Loads

Factors that most influence the prevalence and number of *E. coli* O157:H7 organisms in grinder loads are (1) the size of the *E. coli* O157:H7-contaminated surface area, (2) the effect of chilling on carcasses, and (3) the prevalence and number of *E. coli* O157:H7 organisms in combo bins (both steer/heifer and cow/bull). Table 5-5 shows that *E. coli* O157:H7 contamination in grinder loads is more correlated with the prevalence and number of *E. coli* O157:H7 organisms in steer/heifer combo bins than cow/bull combo bins. Little to no correlation is found between the average number of *E. coli* O157:H7 organisms in combo bins and the number of *E. coli* O157:H7

TABLE 5-4 Correlations with *E. coli* O157:H7 Contamination in Cow/Bull Combo Bins

E. coli O157:H7 Contamination in Cow/Bull Combo Bins	Output Correlations with the Number of *E. coli* O157:H7 Organisms in a Unit and the Percent of Units Contaminated (%) by Season			
	June to September (High Prevalence Season)		October to May (Low Prevalence Season)	
Model Input (factor)	No.	%	No.	%
Area of carcass contaminated	0.33	0.32		0.34
Mean of chilling distribution		0.37		0.36

TABLE 5-5 Correlations with *E. coli* O157:H7 Contamination in Grinder Loads

E. coli O157:H7 Contamination in Grinder Loads	Output Correlations with the Number of *E. coli* O157:H7 Organisms in a Unit and the Percent of Units Contaminated (%) by Season			
	June to September (High Prevalence Season)		October to May (Low Prevalence Season)	
Model Input (factor)	No.	%	No.	%
Cow/bull combos—expected value		0.69		
Cow/bull combos—% contaminated		0.70		0.36
Area of carcass contaminated		0.32		
Mean of chilling distribution		0.34		
Steer/heifer combos—expected value	0.44	0.81	0.33	0.87
Steer/heifer combos—% contaminated		0.97		0.99

organisms in grinder loads. This may be due to the fact that any given grinder load may contain *E. coli* O157:H7 organisms from multiple combo bins, yet the high numbers of *E. coli* O157:H7 organisms in grinder loads are likely caused by the introduction of high numbers of *E. coli* O157:H7 from just one contaminated combo bin. Therefore, the mixing of combo bins to form grinder loads may decrease the influence of combo bin *E. coli* O157:H7 contamination on the average number of *E. coli* O157:H7 organisms in grinder loads.

E. coli O157:H7 in Ground Beef Servings Prior to Storage and Cooking

The number of *E. coli* O157:H7 organisms in grinder loads is an important factor that greatly influences the prevalence and number of *E. coli* O157:H7 organisms in uncooked ground beef servings before storage (Table 5-6). Such a finding is not surprising because the probability of selecting a ground beef serving with 1 or more *E. coli* O157:H7 organisms is dependent on the number of *E. coli* O157:H7 organisms within the grinder load. Table 5-6 indicates that the number of *E. coli* O157:H7-contaminated grinder loads has some influence on the prevalence and density of *E. coli* O157:H7 in uncooked ground beef servings (coefficient: 0.31 to 0.39, October to May). Grinder loads are considered contaminated if they contain at least 1 *E. coli*

TABLE 5-6 Correlations with *E. coli* O157:H7 Contamination in Ground Beef Servings Before the Effects of Growth and Cooking Are Considered

E. coli O157:H7 in Ground Beef Servings Before Storage and Cooking	Output Correlations with the Number of *E. coli* O157:H7 Organisms in a Unit and the Percent of Units Contaminated (%) by Season			
	June to September (High Prevalence Season)		October to May (Low Prevalence Season)	
Model Input (factor)	No.	%	No.	%
Grinders—expected value	0.99	0.95	0.99	0.95
Steer/heifer combos—expected value	0.44	0.40		0.39
Grinders—% contaminated				0.33
Steer/heifer combos—% contaminated				0.31

O157:H7 organism. Because grinder loads are likely to contain 10,000 pounds or more of ground beef, the presence of 1 *E. coli* O157:H7 organism has little effect on whether an individual ground beef serving becomes contaminated with *E. coli* O157:H7.

In general, the more removed an intermediate output (or input) is from a model output, the less influence it has. For example, the occurrence of *E. coli* O157:H7 in steer/heifer combo bins influences the occurrence in grinder loads (Table 5-5). Also, the occurrence of *E. coli* O157:H7 in grinder loads influences the occurrence in servings prior to growth and cooking (Table 5-6). Therefore, the greater influence of *E. coli* O157:H7-contaminated grinder loads relative to *E. coli* O157:H7-contaminated combo bins on the occurrence and extent of *E. coli* O157:H7 contamination in ground beef servings (Table 5-6) simply reflects the closer proximity of ground beef in grinders to ground beef servings in the farm-to-table continuum.

***E. coli* O157:H7 in Ground Beef Servings After Storage and Cooking**

Factors that most influence the occurrence and extent of *E. coli* O157:H7 contamination in consumed ground beef servings (dose) are the prevalence and number of *E. coli* O157:H7 organisms in ground beef servings before storage, the type of storage (e.g., refrigeration versus freezing), the average amount of growth (or decline) in *E. coli* O157:H7 during storage of ground beef servings, and the effect of cooking.

Cooking is notable in its absence from Table 5-7. The effectiveness of cooking is poorly correlated with the exposure distribution in this type of sensitivity analysis because it does not have a wide range of uncertainty (e.g., uncertainty of less than 1 log). In contrast, there is greater uncertainty regarding the growth of *E. coli* O157:H7 during storage (e.g., uncertainty of as much as 2 logs). As a result, the effect of cooking on the amount of *E. coli* O157:H7 in contaminated ground beef servings is revisited in another type of sensitivity analysis (dependency analysis) in the next section.

The uncertainty related to the maximum population density of *E. coli* O157:H7 in ground beef strongly influences the density of *E. coli* O157:H7 in consumed servings (Table 5-7). Uncertainty about the maximum population density for *E. coli* O157:H7 in ground beef servings can range from 5 to 10 logs. This large uncertainty, combined with the importance of this input in the model, accounts for the magnitude of the correlation coefficient (coefficient: 0.58 to 0.60).

TABLE 5-7 Correlations with *E. coli* O157:H7 Contamination in Ground Beef Servings After the Effects of Growth and Cooking Are Considered

E. coli O157:H7 in Ground Beef Servings After Storage and Cooking	Output Correlations with *E. coli* O157:H7 Density and Percent of Units Contaminated (%) by Season			
	June to September (High Prevalence Season)		October to May (Low Prevalence Season)	
Model Input (factor)	Density	%	Density	%
Grinders—expected value	0.35	0.79	0.44	0.78
Max pop density	0.58		0.60	
Growth—expected value	0.82		0.85	
Home/HRI storage temperatures	(0.31)			
Servings before growth and cooking—expected value	0.36	0.78	0.45	0.76
Servings before growth and cooking—% contaminated		0.77	0.39	0.78
Percent ground beef frozen		(0.40)		(0.43)
Steer/heifer combos—expected value		0.36		

The percent of ground beef that is frozen is negatively correlated with the prevalence or density of *E. coli* O157:H7 in consumed servings (Table 5-7). Freezing directly reduces *E. coli* O157:H7 in servings (Sage and Ingham 1998). However, freezing also makes *E. coli* O157:H7 somewhat more heat stable, thereby reducing cooking effectiveness.

The number of *E. coli* O157:H7 organisms in consumed ground beef servings is negatively correlated with home/HRI storage temperatures (Table 5-7). This distribution is modeled using cumulative probabilities. A negative correlation results because lower cumulative probability values are associated with increased occurrence of higher storage temperatures and, consequently, more growth of *E. coli* O157:H7 in ground beef servings.

Previous intermediate outputs, such as grinders, servings before growth and cooking, and steer heifer combos, also influence the occurrence of *E. coli* O157:H7 in consumed ground beef servings (Table 5-7).

Although correlation is one measure of sensitivity, it does not address important inputs that are fixed or relatively certain. The correlation analysis completed for this risk assessment suggests that the *E. coli* O157:H7-contaminated carcass surface area (during slaughter), the average effectiveness of chilling carcasses (slaughter), the maximum population density for *E. coli* O157:H7 in ground beef servings, and home storage (e.g., refrigeration) temperatures are important factors that may influence the occurrence of *E. coli* O157:H7 in consumed ground beef servings and subsequent risk of illness. Nevertheless, some inputs are less uncertain (e.g., cooking effectiveness), yet might be very influential on the exposure to *E. coli* O157:H7 in ground beef and the subsequent risk of illness. Therefore, another type of sensitivity analysis is conducted to identify other factors important in influencing the occurrence of *E. coli* O157:H7 in ground beef and the subsequent risk of illness. This alternative is termed dependency analysis.

Dependency Analysis

Dependency analysis provides insight into the importance of various factors along the farm-to-table continuum that ultimately influence the risk of illness from *E. coli* O157:H7 in ground beef. This type of sensitivity analysis considers the effect of changing parameters for specific factors (model inputs) and examines their effect on intermediate model outputs (occurrence and extent of *E. coli* O157:H7 contamination).

Although some factors (model inputs) do not appear to be correlated (*correlation analysis*) with the occurrence of *E. coli* O157:H7 in consumed ground beef servings and subsequent risk of illness (model outputs), the model outputs might still largely depend (*dependency analysis*) on the values of these inputs. As an example, decontamination steps in slaughter influence the number of *E. coli* O157:H7 organisms remaining on a carcass just prior to trim being generated and placed in combo bins. This effect of decontamination is algebraically determined in the model. However, the parameters describing how decontamination effectiveness varies between carcasses are not very uncertain (varying by only a 0.5 log reduction). In contrast, the most likely value for maximum *E. coli* O157:H7 population density can vary over a 5.0 log range. Therefore, uncertainty about decontamination effectiveness is not substantial enough (i.e., correlation >0.30) to be identified, through correlation analysis, as an important factor influencing the prevalence and number of *E. coli* O157:H7 in combo bins. Instead, this factor would be identified through the use of dependency analysis.

Because this risk assessment involves complicated relationships among model inputs, dependency analysis illustrates the effect of changing model inputs on intermediate model outputs (i.e., the occurrence and extent of *E. coli* O157:H7 contamination in ground beef along the farm-to-table continuum). The analysis is conducted by developing different scenarios where some model inputs are intentionally changed and the resultant outputs are compared with model outputs generated from a baseline scenario (i.e., where all model inputs are unchanged).

Production and Slaughter Modules

Because production and slaughter module inputs both influence the *E. coli* O157:H7 contamination that occurs in combo bins, their dependency analysis is completed in tandem.

This analysis is limited to simulating steer/heifer slaughter establishments during the high prevalence season (June to September). The simulations only consider cattle contaminated during the dehiding step in slaughter. Model inputs that are not evaluated in the dependency analysis are held at their median values.

Although the scope of this dependency analysis is limited, it is reasonable to assume that its results will also describe proportional changes occurring in cow/bull slaughter plants, as well as in both types of plants during the low prevalence season. Besides feedlot and within-feedlot prevalence, no other model inputs to the slaughter module differ dramatically between the seasons.

<u>Simulated Scenarios for Production and Slaughter</u>

Scenarios were simulated that change, in turn, feedlot *E. coli* O157:H7 prevalence, within-feedlot *E. coli* O157:H7 prevalence, decontamination following dehiding, steam pasteurization following evisceration, the live cattle to carcass transformation ratio, and the effect of carcass chilling. Changes to these model inputs for each scenario were as follows:

- *Feedlot prevalence scenario*—changes the value for feedlot *E. coli* O157:H7 prevalence from 88% to 44% (a 50% change).

- *Within-feedlot scenario*—changes the value for average within-feedlot *E. coli* O157:H7 prevalence from 22% to 11% (50% change).
- *Decontamination following dehiding scenario*—changes the effectiveness of decontamination from a most likely range of 0.3 and 0.7 logs (baseline) to a uniform decontamination effectiveness of 1.2 logs (i.e., assumes there is always maximum effectiveness of decontamination following dehiding).
- *Steam pasteurization scenario*—changes the effectiveness of decontamination from a most likely range of 0.5 to 1.5 logs (baseline) to a uniform decontamination effectiveness of 2.5 logs (i.e., assumes there is always maximum effectiveness of steam pasteurization).
- *Live cattle to carcass transformation ratio scenario*—changes the distribution ranging from 1 to 2 to a constant of 1 (i.e., this scenario assumes a lowest possible ratio of *E. coli* O157:H7-contaminated carcasses to infected live cattle). This scenario suggests greater control of *E. coli* O157:H7 contamination during the dehiding step when live cattle are converted to carcasses.
- *Carcass chilling effect scenario*—changes the standard deviation for chilling in the baseline scenario to zero (i.e., assumes carcass chilling has no effect in either increasing or decreasing the number of *E. coli* O157:H7 organisms on carcasses). Although correlation analysis has already shown that the carcass chilling step is important in predicting *E. coli* O157:H7 contamination in combo bins, a scenario for this input is simulated for illustration.

Results of the Simulated Scenarios for Production and Slaughter

Figure 5-4 shows the results of these scenario analyses. All of the scenarios resulted in a lower number of *E. coli* O157:H7-contaminated combo bins compared with the baseline scenario (i.e., no changes). That is, all scenarios resulted in less than 40% (baseline) of combo bins containing 1 or more *E. coli* O157:H7 organisms.

The most effective decontamination scenario was the assumption of a 2.5 log reduction in the number of *E. coli* O157:H7 organisms on carcasses from steam pasteurization. The *steam pasteurization scenario* resulted in a 75% reduction in the number of *E. coli* O157:H7-contaminated combo bins compared with the baseline scenario. The *decontamination following dehiding scenario* results in about an 50% reduction in the number of *E. coli* O157:H7-contaminated combo bins compared with the baseline scenario. Both decontamination after dehiding and steam pasteurization generally reduced the number of *E. coli* O157:H7 organisms on contaminated carcasses and in subsequent combo bins. Steam pasteurization has a greater influence than decontamination after dehiding in these scenarios because its effectiveness is 2.5 logs versus 1.2 logs for decontamination after dehiding.

Reducing feedlot prevalence by 50% results in a 43% reduction in the number of *E. coli* O157:H7-contaminated combo bins. A similar reduction in within-feedlot prevalence results in only a 25% reduction in the number of *E. coli* O157:H7-contaminated combo bins. Feedlot prevalence determines the proportion of truckloads that arrive with one or more infected cattle. Within-feedlot prevalence is variable between contaminated truckloads, and it determines how many infected cattle there are among the 40-head capacity of these trucks. Therefore, the influence of feedlot prevalence on the incoming prevalence of infected cattle is somewhat more direct than the influence of within-feedlot prevalence.

The distribution for the *transformation ratio scenario* generally parallels the distribution for the within-feedlot prevalence scenario but is slightly less effective. On average, there are about 1.5 *E. coli* O157:H7-contaminated carcasses per infected live animal (e.g., cross-contamination).

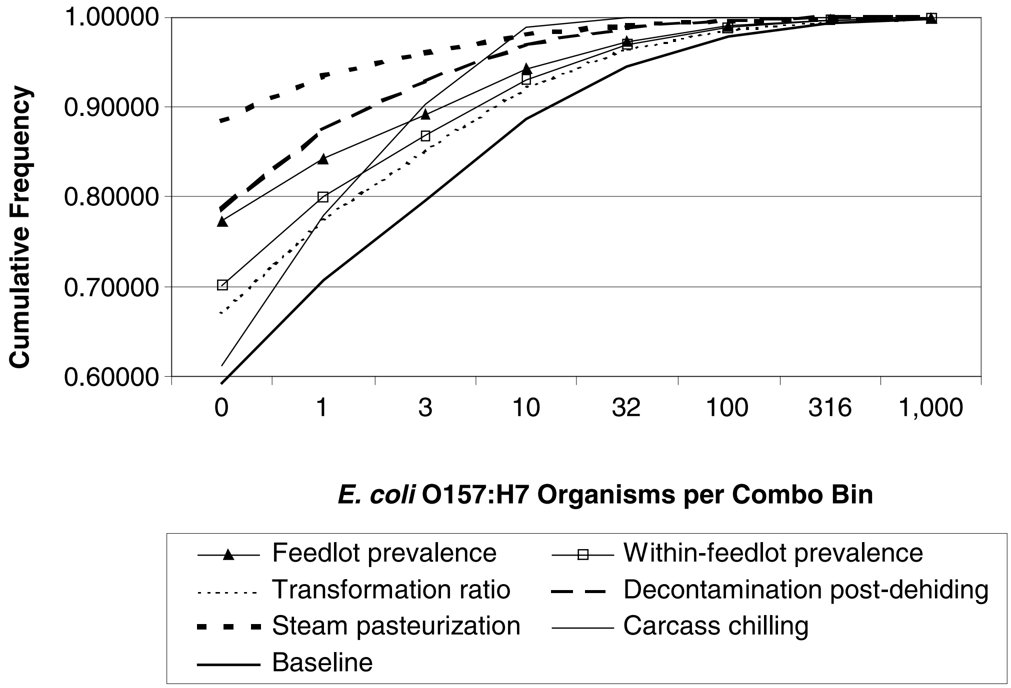


FIGURE 5-4 Comparison of cumulative distributions of combo bin contamination for six scenarios relative to baseline. Feedlot and within-feedlot prevalence scenarios reduce these inputs by 50%. The decontamination and steam pasteurization scenarios assume a constant maximum effectiveness of these steps.

Therefore, this scenario assumes about a one-third reduction in this input relative to the baseline scenario. This magnitude of reduction is less than that resulting from the 50% reduction in within-feedlot prevalence and explains the discrepancy between the respective distributions. It is expected that modeling a 50% reduction in the transformation ratio would result in a shift in the combo bin contamination distribution similar to that shown for the within-feedlot prevalence scenario. However, a 50% reduction in the transformation ratio would be beyond the bounds of the current uncertainty distribution.

Carcass chilling had little effect on the number of *E. coli* O157:H7-contaminated combo bins. However, in this scenario, there was a dramatic reduction in the occurrence of high levels of *E. coli* O157:H7 in combo bins relative to other scenarios. Because the influence of carcass chilling on individual combo bins can range from –3 to +3 logs in the baseline scenario, this step can result in substantial amplification of *E. coli* O157:H7 on carcasses and in combo bins. This scenario illustrates that high numbers of *E. coli* O157:H7 organisms in combo bins are primarily the result of increases in the number *E. coli* O157:H7 organisms on carcasses during chilling. Furthermore, this scenario illustrates that the high numbers of *E. coli* O157:H7 organisms in combo bins are influenced by the high numbers of *E. coli* O157:H7 organisms that occur occasionally on chilled carcasses. This suggests that chilling carcasses is an important factor that greatly influences the number of *E. coli* O157:H7 in beef trim in combo bins.

While all of these factors are important in influencing *E. coli* O157:H7 contamination in ground beef, it may be more important to focus mitigation strategies on areas that influence the occurrence of *E. coli* O157:H7-contaminated ground beef servings (e.g., steam pasteurization) than on those that influence the number of *E. coli* O157:H7 in a contaminated serving (e.g., carcass chilling). As noted in the "*Risk of E. coli O157:H7 Illness as a Function of Exposure*

(Dose)" section, population risk of illness may be influenced more by prevalence of *E. coli* O157:H7-contaminated ground beef servings than by the level of *E. coli* O157:H7 in contaminated servings (dose).

Preparation Module

The preparation module primarily consists of creating, storing, and cooking ground beef servings. In the correlation analysis, storage temperature, proportion of ground beef that is frozen, and the amount of growth during storage were the most influential factors contributing to the occurrence and extent of *E. coli* O157:H7 in consumed ground beef servings (Table 5-7). However, there was no demonstrated correlation with cooking temperature or the log reduction expected from cooking. Therefore, the effects of cooking temperature and storage conditions on the occurrence and extent of *E. coli* O157:H7 contamination in consumed ground beef servings is considered as part of "what if" scenarios (dependency analysis).

<u>Simulated Scenarios for Preparation</u>

The following scenarios were considered:

1. *No growth during storage scenario*—assumes that all ground beef servings are stored to ensure that no growth takes place at retail, from retail to the home/HRI, and while stored at the home/HRI.
2. *Cooking to 5 log reduction scenario*—assumes that all ground beef servings are cooked to ensure at least a 5 log reduction in *E. coli* O157:H7 organisms. In this scenario, the median cooking distribution is applied except for those ground beef servings that would have less than a 5 log reduction. These ground beef servings are modeled such that a 5 log reduction occurs.
3. *No growth during storage and 5 log reduction during cooking scenario*—assumes all ground beef servings are stored to ensure that no growth takes place and, in addition, are all cooked to ensure at least a 5 log reduction in *E. coli* O157:H7 organisms.

<u>Results of the Simulated Scenarios for Preparation</u>

Figure 5-5 shows the median exposure distribution from the baseline model and the resultant exposure distributions from each of the three scenarios in this sensitivity analysis. Each scenario results in a reduction in the prevalence of *E. coli* O157:H7-contaminated servings relative to the baseline scenario. The *no growth during storage scenario* results in a 7% decrease in the number of *E. coli* O157:H7-contaminated ground beef servings. The *cooking to 5 log reduction scenario* results in a 93% decrease in the number of *E. coli* O157:H7-contaminated servings. The third scenario, combining the effect of no growth during storage and cooking to a 5 log reduction, results in a 99.99% decrease in the number of *E. coli* O157:H7-contaminated ground beef servings.

Ensuring at least a 5 log reduction from cooking reduces the maximum number of *E. coli* O157:H7 organisms per ground beef serving (dose) to which individuals could be exposed. Exposures that remain after all servings have at least a 5 log reduction applied demonstrate that there can be enough growth to overcome the effect of cooking. Ensuring that no growth takes place also reduces the maximum dose of *E. coli* O157:H7 in ground beef to which individuals could be exposed. In this case, there can be no more *E. coli* O157:H7 organisms in a ground beef serving than were originally present when the servings were generated from grinder loads. Because a small proportion (4% to 8%) of the U.S. population grossly undercooks (i.e., little or

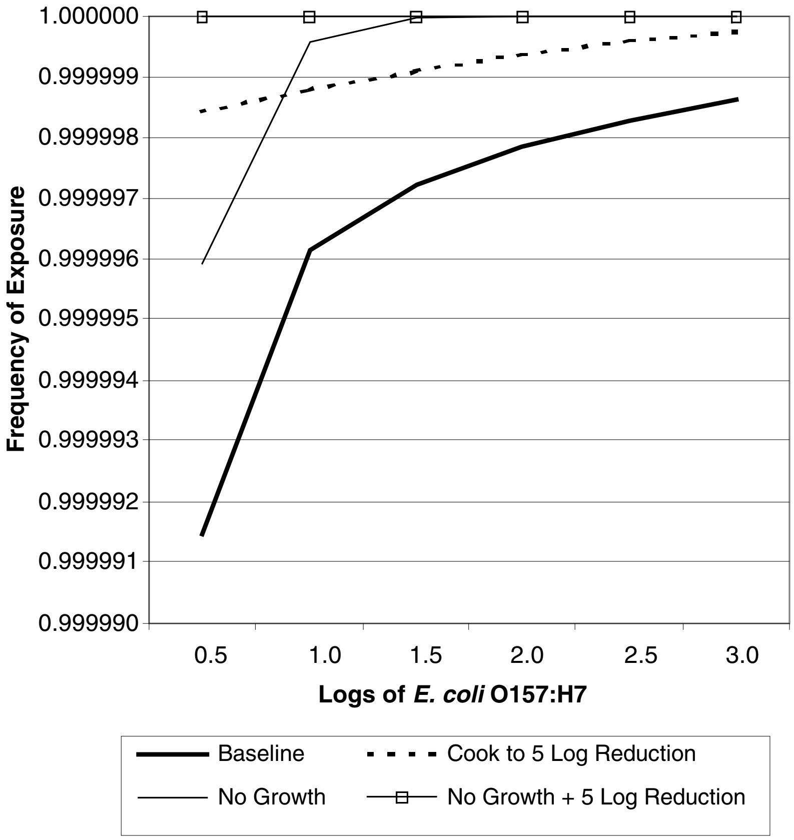


FIGURE 5-5 Reduction in the number of *E. coli* O157:H7 organisms per ground beef serving for three scenarios relative to a baseline scenario. One scenario assumes no growth of *E. coli* O157:H7 during storage. The second scenario assumes that cooking of all products ensures at least a 5 log reduction. The third scenario combines no growth and a 5 log reduction from cooking.

no log reduction in the number of *E. coli* O157:H7) ground beef servings, the *no growth during storage scenario* still allows exposure of up to 2 logs of *E. coli* O157:H7 per ground beef serving.

Virtually no risk of *E. coli* O157:H7 illness exists if ground beef servings are handled in such a way that no growth occurs and are cooked in such a way as to ensure a minimum of a 5 log reduction in the number of *E. coli* O157:H7 organisms. Such a finding may be reassuring to consumers. However, since consumers do not have complete control over the product (i.e., storage conditions at retail), it is possible for sufficient growth to take place that a 5 log reduction through cooking is not enough to render the product safe.[13]

Comparing the effects of storage and cooking implied by this analysis suggests that ensuring adequate cooking may be more important than controlling the growth of *E. coli* O157:H7 in servings. Cooking was not identified in the correlation analysis. Demonstrating its importance, therefore, requires dependency analysis. Furthermore, this dependency analysis has clearly shown that controlling both cooking and growth can substantially reduce the probability of exposure to *E. coli* O157:H7 in ground beef.

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[13]FSIS recommends that consumers cook their hamburgers to 160°F (internal product temperature) and use a meat thermometer.

CONCLUSIONS

The *E. coli* O157:H7 risk assessment is a practical tool that can be used to evaluate various intervention strategies to control and prevent the occurrence and extent of *E. coli* O157:H7 contamination in ground beef. This risk characterization provides information on the risk of illness from *E. coli* O157:H7 in ground beef for an individual, a community, and the entire U.S. population. Variability in the population risk of illness from *E. coli* O157:H7 in ground beef is considered based on differences in seasonal exposure and age of the consumer. The risk characterization also provides information regarding which factors have the greatest influence on the occurrence of *E. coli* O157:H7 in combo bins, grinder loads, and ground beef servings and on subsequent risk of illness. The results of the risk characterization are summarized below.

Risk of Illness from *E. coli* O157:H7 in Ground Beef

- An illustrative example of the risk of illness from *E. coli* O157:H7 in ground beef was used to show how this model could calculate risk for individuals. A "typical" individual's annual risk of illness from *E. coli* O157:H7 in ground beef is between 1 in 600 million servings and 1 in 400 billion servings.
- The *E. coli* O157:H7 risk assessment was used to illustrate a foodborne outbreak scenario for a community in which a grinder load of ground beef was stored improperly and the number of *E. coli* O157:H7 in it reached 5.5 logs per serving. If all of these servings were undercooked (e.g., served by the same restaurant) and individuals consume only one of these servings, then about 3,200 people would be expected to become ill. On the other hand, if all of these contaminated ground beef servings had been subjected to similar cooking conditions that resulted in a decrease of 5.5 logs, only 12 people would be expected to become ill from *E. coli* O157:H7.
- The annual risk of illness from *E. coli* O157:H7 in ground beef for the general U.S. population is nearly 1 illness in 1 million servings of ground beef (9.6×10^{-7}). This corresponds to a risk of being hospitalized and recovering of 2.0×10^{-8} per serving, developing HUS and recovering of 4.2×10^{-9} per serving, and death of 5.9×10^{-10} per serving.
- Most contaminated cooked ground beef servings contain only 1 *E. coli* O157:H7 organism. The subsequent probability of illness given an exposure of 1 *E. coli* O157:H7 organism in a ground beef serving is low. Therefore, this results in a low risk of illness from *E. coli* O157:H7 in a ground beef serving.
- Few contaminated cooked ground beef servings contain 100,000 *E. coli* O157:H7 organisms per serving (1.8×10^{-7}). The probability of illness at this dose is 0.58. This results in the highest risk of illness (1.0×10^{-7}) from *E. coli* O157:H7 in a ground beef serving (see Table 5-1 and Figure 5-1).
- Reducing the number of *E. coli* O157:H7-contaminated ground beef servings may reduce risk of illness more than reducing the amount of *E. coli* O157:H7 in contaminated servings.

Population Risk Variabilty

- The risk of *E. coli* O157:H7 illness is about three times higher during June to September than during October to May.

- The risk of *E. coli* O157:H7 illness is, hypothetically, about 2.5 times higher for children ages 0 to 5 (2.4×10^{-6} per serving) than for the general U.S. population (9.6×10^{-7}). This estimate is based on the assumption that children under 5 years of age are more susceptible to illness from exposure to *E. coli* O157:H7 while consuming only about 7% of all ground beef servings and smaller serving sizes.

Sensitivity Analysis

Correlation Analysis

- The size of the *E. coli* O157:H7-contaminated carcass surface area is an important factor that most influences the occurrence of *E. coli* O157:H7 in steer/heifer combo bins (see *Sensitivity Analysis*, Table 5-2).
- The size of the *E. coli* O157:H7-contaminated carcass surface area and the effects of carcass chilling are factors that most influence the occurrence of *E. coli* O157:H7 in cow/bull combo bins (see *Sensitivity Analysis*, Table 5-3).
- The occurrence and extent of *E. coli* O157:H7 contamination in cow/bull and steer/heifer combo bins, the size of the *E. coli* O157:H7-contaminated carcass surface area, and the effects of carcass chilling are factors that most influence the occurrence of *E. coli* O157:H7 in grinder loads (see *Sensitivity Analysis*, Table 5-4).
- The occurrence of *E. coli* O157:H7 in grinder loads and in steer/heifer combo bins are factors that most influence the occurrence of *E. coli* O157:H7 in uncooked ground beef servings (see *Sensitivity Analysis*, Table 5-5).
- The number of *E. coli* O157:H7 organisms in steer/heifer combo bins and grinder loads as well as the maximum population density for *E. coli* O157:H7 per ground beef serving, growth of *E. coli* O157:H7 during storage and handling, storage temperatures, and the percent of ground beef that was frozen are factors that most influence the occurrence and extent of *E. coli* O157:H7 in consumed ground beef servings (see *Sensitivity Analysis*, Table 5-6).

Dependency Analysis

- If steam pasteurization was 100% effective (e.g., always resulted in a 2.5 log reduction in the number of *E. coli* O157:H7 organisms on carcasses), then the number of *E. coli* O157:H7-contaminated combo bins would decline by 75% compared with the baseline scenario. This was the most effective scenario considered in reducing the number of *E. coli* O157:H7-contaminated combo bins.
- If decontamination following dehiding always maintained a maximum effectiveness of a 1.2 log reduction in the number of *E. coli* O157:H7 organisms on carcasses, then the number of *E. coli* O157:H7-contaminated combo bins would decrease 50% (see *Sensitivity Analysis*, Figure 5-4).
- Reducing feedlot prevalence by 50% results in a 43% reduction in the number of *E. coli* O157:H7-contaminated combo bins. A similar reduction in within-feedlot prevalence results in only a 25% reduction in the number of *E. coli* O157:H7-contaminated combo bins (see *Sensitivity Analysis*, Figure 5-5).
- Carcass chilling had little effect on the number of *E. coli* O157:H7-contaminated combo bins but had a large effect on the amount of *E. coli* O157:H7 in contaminated combo

bins. Large numbers of *E. coli* O157:H7 organisms in combo bins are primarily the result of occasionally high numbers of *E. coli* O157:H7 on chilled carcasses (e.g., improper chilling) (see *Sensitivity Analysis*, Figure 5-6).

- Both growth of *E. coli* O157:H7 in contaminated ground beef servings during storage and reduction in the number of *E. coli* O157:H7 organisms during cooking are factors that most influence the occurrence and extent of *E. coli* O157:H7 contamination in ground beef servings. The dependency analysis indicates that adequate cooking may be more important than controlling the growth of *E. coli* O157:H7 in ground beef servings. Virtually no risk of *E. coli* O157:H7 illness exists from ground beef servings that are stored and handled under conditions that do not allow growth to occur and are sufficiently cooked to ensure a minimum of a 5 log reduction in the number of *E. coli* O157:H7 organisms (see *Sensitivity Analysis*, Figure 5-5).

LIMITATIONS

When approaching this risk assessment, it is important to understand its scope, purpose, and data limitations. First, the scope of this risk assessment was limited to ground beef because epidemiological evidence indicated it was the primary foodborne vehicle for exposure to *E. coli* O157:H7 (see Chapter 2). Ground beef servings were those from patties, sandwiches, meat loaf, and meatballs in which the ground beef could potentially be undercooked and have viable *E. coli* O157:H7. Foods consisting of granulated ground beef and intact and nonintact (e.g., tenderized) cuts of beef, such as steaks and roasts, were not included in the risk assessment. These foods were excluded because the associated risk of exposure to *E. coli* O157:H7 is thought to be low based on epidemiological evidence and input from the National Advisory Committee for Microbiological Criteria for Foods (NACMF, December 2000). This risk assessment, however, will be used to develop risk assessments for *E. coli* O157:H7 in other beef products (e.g., nonintact beef).

Second, the effect of differences in the food matrix on *E. coli* O157:H7 survival and growth were not included in this risk assessment because of lack of data. Although the included ground beef products are similar, matrix differences such as salt, water activity, pH, and spices likely vary between these foods.

Third, the contribution of cross-contamination to *E. coli* O157:H7 exposure was also not included due to a lack of data. For example, there is little to no information about the proportion of foodborne outbreaks or sporadic cases of *E.* coli O157:H7 infection that are due to exposure to a nonbeef food item that was cross-contaminated by beef (e.g., lettuce). Cross-contamination of salad bar and other food items was thought to be the cause of four outbreaks that occurred in four separate restaurants in two states during 1993–1994 (Jackson et al. 2000). Interestingly, the implicated beef item in these outbreaks was not ground beef but was an intact cut of beef that was tenderized by maceration at the restaurant.

Fourth, the derivation of the dose-response function in hazard characterization was based on *E. coli* O157:H7 illnesses in the general population without further differentiation for sensitive subpopulations, such as children or the elderly. While it was assumed that children ages 0 to 5 are more susceptible and might have a dose-response function similar to the *E. coli* O157:H7 dose-response upper bound function (derived from *Shigella dysenteriae* clinical studies), supporting foodborne illness surveillance data are needed to validate this assumption.

Finally, the derived *E. coli* O157:H7 dose-response function did not take into consideration any differences in pathogenicity among *E. coli* O157:H7 strains.

RESEARCH NEEDS

An important benefit of conducting a risk assessment is the identification of data and knowledge gaps. Through the collection and evaluation of data for this risk assessment, it became apparent that specific information and data would enhance the certainty of the risk assessment estimates. The determination of which data would be most beneficial is based on areas identified as important (sensitivity analysis) *and* for which there is limited information. Food safety research needed to fill existing data gaps and enhance this risk assessment is discussed below.

Hazard Identification

- Information on the maximum density of *E. coli* O157:H7 organisms in ground beef servings as a result of matrix effects, competitive microflora in ground beef, and environmental conditions (e.g., pH, water activity).[14]
- Predictive microbiological data on the increase and decrease in the number of *E. coli* O157:H7 organisms in ground beef under various storage and preparation conditions along with frequencies of occurrence of these storage and preparation conditions.

Exposure Assessment

- Additional information on *E. coli* O157:H7 contamination on carcasses following dehiding.
- Data on cross-contamination of *E. coli* O157:H7 between carcasses during carcass splitting.
- Time-temperature data (quantitative) for chillers in slaughter establishments.
- Marketing data on the proportion of beef ground at slaughter versus at retail.
- Data on retail (HRI) and consumer storage, cooking, and consumption (frequency and serving size) patterns by type of ground beef meal (e.g., grilled hamburger in July and baked meat loaf in October).

Hazard Characterization (Dose-Response Data)

- Number and severity of illness among children ages 0 to 5 from *E. coli* O157:H7 in ground beef (response data). These data may come from surveillance data or from foodborne outbreak data.[15]
- Dose-response data from foodborne outbreaks of *E. coli* O157:H7 in ground beef servings (e.g., the number of *E. coli* O157:H7 organisms in a serving and resulting severity of illness).

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[14]There is considerable uncertainty regarding the maximum population density in ground beef servings due to competitive microflora (see Chapter 3). The risk assessment includes an uncertainty range of 5 to 10 logs of *E. coli* O157:H7 for the maximum population density in ground beef servings.

[15]For all outbreaks, the line listing should include month and year of occurrence and the number of ill persons per outbreak. For foodborne outbreaks, the line listing should include month and year of outbreak occurrence, county and state of occurrence, number of ill persons, number hospitalized, number with severe outcome (e.g., stillbirth/miscarriage for *Listeria monocytogenes*, HUS/TTP for *E. coli* O157:H7), number of deaths, specific vehicle implicated (e.g., not just "beef" but ground beef, roast beef etc.), and detailed comments about sensitive subpopulations, (e.g., immunocompromised persons in an outbreak of *L. monocytogenes*, ages of persons with HUS, age and health status of persons who died).

- Descriptive epidemiologic information about sporadic cases of *E. coli* O157:H7 illness, including the month of disease onset, age, sex, hospitalizations, summary of clinical manifestations including severe disease manifestations, and food vehicles involved (if known).
- Additional case-control studies of sporadic *E. coli* O157:H7 cases to calculate etiologic fraction attributable to ground beef.

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